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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,362	12/12/2003	Diana J. Parsons	parsons 3	1804
40198 7590 09/07/2007 BUSH INTELLECTUAL PROPERTY LAW GROUP, LLC P.O. BOX 381146 BIRMINGHAM, AL 35238				
			EXAMINER LANDAU, SHARMILA GOLLAMUDI	
			ART UNIT 1616	PAPER NUMBER
			MAIL DATE 09/07/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/735,362	Applicant(s) PARSONS, DIANA J.	
	Examiner Sharmila Gollamudi Landau	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 June 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21, 23-29 and 33-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21, 23-29, 33-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt of Request for Continued Examination and Amendments/Remarks filed 6/22/07 is acknowledged. Claims 1-20, 22, and 30-32 stand cancelled. Claims 21, 23-29, 33-37 are pending.

Withdrawn Rejections

1) The rejection of claims 21, 23, 26-29, 33-37 under 35 U.S.C. 103(a) as being unpatentable over Tankovich et al (6,050,990) in view of Ho et al (Dermatologic Surgery. 1995 December, 21(12), 1035-7) and Kye YC (Dermatologic Surgery 1997 October, 23(10): 880-883) is withdrawn in light of the amendments of 6/22/07.

2) The rejection of claims 24-25 under 35 U.S.C. 103(a) as being unpatentable over Tankovich et al (6,050,990) in view of Ho et al (Dermatologic Surgery. 1995 December, 21(12), 1035-7) and Kye YC (Dermatologic Surgery 1997 October, 23(10): 880-883) in further view of Obagi (4,874,361) is withdrawn in light of the amendments of 6/22/07.

Specification

The amendment filed 6/22/07 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: "by the method described in Tankovich (US 6,036,684)... Since the skin is exposed to laser pulse at a frequency of about 1 Hz only one pass of the laser light is required...." Note that the entire added text (underlined portion) is considered new matter.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21, 23-29, 33-37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant has amended the claims to recite, "with one pass of laser light" which does not have support in the originally filed specification. Further, the recitation, "does not remove skin or hair" does have support in originally filed specification. It is noted that applicant has amended the specification to add the new matter. The *originally* filed specification disclosed, "The energy from the laser is adjusted to be just sufficient to cause the particles to explode. As the particles explode, they cause the removal of the stratum corneum and the mineral oil 20 penetrates into the epidermis producing hydration of the epidermis by retarding the evaporation of water (see Fig. 2)."

It should be noted that once the new matter is removed, the examiner will reinstate all the withdrawn rejections.

Claims 21, 23-29, 33-37 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for does not remove hair does not reasonably provide enablement for does not remove skin. The specification does not enable any person

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skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

Enablement is considered in the view of the Wands factors (MPEP 2164.01 (a)). These include the nature of the claims, guidance of the specification, the existence of working examples, predictability of the prior art, and state of the prior art. All of the Wands factors have been considered with the regard to the instant claims, with the most relevant discussed below. The instant claims are not enabled to prevent healing of the skin indefinitely and the process of treatment by prevention of healing.

Nature of the Invention: The rejected claims are drawn to the method of producing sustained skin rejuvenation comprising: a) pre-treating the skin with a retinoic acid; b) exploding a contaminant on the skin surface without removing skin or hair using a wavelength of 800-1200nm, a fluence of 1-3 J/cm², and a pulse duration of 0.001-1 microsecond; c) applying retinoic acid to the skin 4-16 times after step b, and d) repeating treatment once every twelve months.

Breadth of the claims: The breadth of the claim encompasses preventing any skin removal after exploding a contaminant such as graphite or carbon using a laser.

Guidance of the Specification: The guidance provided by the amended specification page 7 discloses that only one laser pulse exposure at about 1Hz does not remove hair or skin since at least 3 pulse are required to remove the stratum corneum as evidenced by US 6,036,684. The specification as originally filed, page 7, discloses, "The energy from the laser is adjusted to be just sufficient to cause the particles to explode. As the particles explode, they cause the

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removal of the stratum corneum and the mineral oil 20 penetrates into the epidermis producing hydration of the epidermis by retarding the evaporation of water (see Fig. 2)."

The State of the Art: US 6,036,684, to Tankovich, teaches an identical process using the same fluence, pulse duration, and wavelength. Tankovich discloses that a single pulse using a graphite particle, which is exploded violently upon being illuminated by vaporizes, i.e. removes, remove a first layer of skin, the second pulse vaporizes the second layer of skin and so forth. Therefore, the state of the art indicates that the same process does remove some skin. The laser art indicates that there is nonablative and ablative laser surgery. In ablative laser surgery, a laser works by vaporizing the top layer of the skin to remove blemishes, scars and wrinkles. In non-ablative laser surgery, the laser is capable of removing tissue beneath the first layer of skin (in the epidermis). See <http://www.plasticsurgeryadvisor.com/skin-resurfacing-surgery/non-ablative-laser-surgery.shtml>. Therefore, the prior art indicates that some skin either in the stratum corneum or beneath the stratum corneum will be removed by laser surgery.

Working Examples: The specification does not contain working examples.

Predictability of the Art: The lack of significant guidance from the specification or the prior art with regard to preventing the removal of any skin by exploding a contaminant using lasers makes practicing the instant invention unpredictable.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 21, 23-29, 33-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldberg et al (Skin resurfacing utilizing a low-fluence Nd:YAG laser, J Cutan Laser Ther. 1999;1:23-27) in view of in view of Alster (Combined Laser Resurfacing and Tretinoin Treatment of Facial Rhytides, Cosmetic Dermatology, Volume 10, No. 11, November 1997) in view of Ho et al (Dermatologic Surgery. 1995 December, 21(12), 1035-7) and Kye YC (Dermatologic Surgery 1997 October, 23(10): 880-883).

Goldberg et al teach nonablative skin resurfacing using 1064-nm Q-switched Nd:YAG laser potentiated by a carbon solution at a fluence of 2.5J/cm, repetition rate of 1-10 HZ, and a pulse duration of 6-20ns to treat rhytides (wrinkles). The treatment sites were treated at 4 and 8 weeks. Improvement in wrinkles, skin texture, and elasticity was seen. See abstract.

Goldberg does not teach the application of retinoic acid.

Alster teaches cutaneous laser resurfacing recently has advanced the treatment of facial rhytides (wrinkles) to provide a youthful look. Combining laser resurfacing with long-term skin care using tretinoin emollient cream provides maximal, long-lasting improvement of facial rhytides. See abstract. Alster teaches the benefits of tretinoin emollient cream in the treatment of photodamage have been increasingly recognized during the past several years. Although the

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mechanism of action remains unclear, tretinoin emollient cream has been shown to induce collagen synthesis and decrease the breakdown of collagen, to increase epidermal mucin, to decrease elastosis and epidermal melanin, and to improve organization and promote new synthesis of papillary dermal collagen. The greatest clinical improvements to photodamaged skin with the use of tretinoin emollient cream have been noted in fine wrinkling, mottled, hyperpigmentation, and skin roughness. See page 41. 0.05% applied nightly is disclosed.

Ho et al teach laser resurfacing in pigmented skin and skin with acne scars with a CO₂ laser. The method includes: (a) The patients were treated with 0.05% tretinoin, hydroquinone, and desonide cream nightly for 2-4 weeks prior to the laser treatment (b) The Ultrapulse 5000C CO₂ laser with a setting of 250-450 mJ per pulse, or the Silk-Touch flashscanner at the setting of 5-7 W, 0.2-second pulse duration, and 4-mm (M) spot size, is used on the skin; (c) tretinoin, hydroquinone, and desonide and broad spectrum sunscreen is also used postoperatively. Ho discloses the reduction of hyperpigmentation with regular use of tretinoin, hydroquinone, and desonide cream both pre- and postoperatively along with use of broad-spectrum sunscreen after treatments. See abstract.

Kye teaches a method of resurfacing pitted facial scars including acne scars, chicken pox scar, and small pox scars, with a pulsed Er:YAG laser. The method includes: step (a) prior to laser surgery, the patients are treated with 0.05% tretinoin (note 0.05% reads on about 0.1%) nightly for two to four weeks; step (b) the patient is then treated with Er:YAG laser at a setting of 500mJ/pulse and 3.5-4.5 Watts with a pulse frequency of 7-9 Hz. Kye discloses that after 4-6 laser passes, pinpoint bleeding occurred; step (c) two weeks after laser treatment % tretinoin and 1% hydrocortisone cream is applied for 2-4 weeks. See abstract.

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the above references and utilize a pre-treatment and post-treatment regimen prior to the laser therapy taught by Goldberg. One would have been motivated to do so since Alster teaches combining laser resurfacing with long-term skin care using tretinoin emollient cream provides maximal, long-lasting improvement of facial rhytides. Therefore, it is prima facie obvious for a skilled artisan to utilize tretinoin to work in conjunction with laser treatment to provide long lasting results.

Further, Ho and Kye both teach the use of tretinoin both pre- and postoperatively. Ho teaches the reduction of hyperpigmentation after laser resurfacing is reduced with regular use of tretinoin, hydroquinone, and desonide cream, both pre- and postoperatively. Thus, Kye and Ho establish the state of the art wherein it is known and conventional to utilize retinoic acid as part of the pre-laser and post-laser regimen. hyperpigmentation.

With regard to step (d) in claim 21, Goldberg teaches repeated treatment. Therefore, it is within the skill of an artisan to repeat laser therapy based on the desired result and maintenance for a certain cosmetic condition. For instance, a skilled artisan would be motivated to maintain the treatment as long as required to maintain healthy and young skin including at least once every twelve months or more. It is noted that Goldberg is silent to the number of passes. It appears that the laser is only passed once since Goldberg does not teach passing the laser multiple times. Moreover, the manipulation of the number of laser passes is within the skill of an artisan since it depends on patient parameters. For instance, mild rhytides would only require one pass of the laser.

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With regard to claim 36, tretinoin is known and routinely used to treat acne as evidenced by Kye. Therefore, a skilled artisan would have expected the process as claimed in claim 21 to treat acne.


Conclusion

All the claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila Gollamudi Landau whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Sharmila Gollamudi Landau
Primary Examiner
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